Opsumit® REMS Inpatient Pharmacy Enrollment Form

Complete and fax this form to *Actelion Pathways*® at 1-866-279-0669.

You can also reach *Actelion Pathways* via phone at 1-866-ACTELION (1-866-228-3546)

HO2201512

Due to the risk of teratogenicity for female patients, Opsumit is available only through a restricted program called the Opsumit REMS (Risk Evaluation and Mitigation Strategy) Program. In order for inpatients to receive Opsumit, females, as well as inpatient pharmacies that wish to stock this product, must enroll in the Opsumit REMS Program and agree to comply with the requirements of the program. An Authorized Representative must complete and submit this form on behalf of the inpatient pharmacy.

Inpatient pharmacy information (please print)

Name

☐ Hospital ☐ Nursing home ☐ Hospice ☐ Asylum/Mental facility ☐ Assisted Living ☐ Prison ☐ Rehabilitation

☐ Other (please specify): _____

Identification (please complete one of the following):

☐ Health Industry Number (HIN #) _____ ☐ National Provider Identifier (NPI #) _____

☐ Other identifier: _____

Address

City | State | ZIP

Phone # | Fax #

Ship to address (if different from above)

Address

City | State | ZIP

Phone # | Fax #

Authorized Representative information (please print)

Name

Title:

☐ Hospital pharmacist ☐ Head of Pharmacy and Therapeutics (P&T) committee

☐ Other title: _____

Authorized Representative phone # | Fax #

Authorized Representative email

Authorized Representative consent

This inpatient pharmacy will:

- Put processes and procedures in place to ensure the Opsumit REMS Program requirements are met
- Dispense only to those patients under the supervision and care of a healthcare provider who is enrolled in the Opsumit REMS Program
- Dispense to a female patient only after she has been enrolled in the Opsumit REMS Program or if she will be enrolled prior to discharge from this healthcare facility. A female who has not been enrolled by the certified prescriber will not have access to Opsumit in the outpatient setting until such time that registration has been completed
- Dispense no more than a fifteen- (15-) day temporary supply of Opsumit upon discharge of any patient
- Notify Actelion Pharmaceuticals US, Inc. ("Actelion") or FDA if any patient becomes pregnant during Opsumit treatment
- Not transfer Opsumit to any pharmacy, practitioner, or any healthcare setting not certified by *Actelion Pathways*
- Develop a process to track compliance with the conditions above and provide information about its compliance to Actelion

I attest that I have read the Opsumit Prescribing Information, *Medication Guide*, and *Prescriber and Pharmacy Guide for the Opsumit REMS Program* available at www.OpsumitREMS.com.

I will ensure training of dispensing staff on the Opsumit REMS Program procedures and materials, including the *Prescriber and Pharmacy Guide for the Opsumit REMS Program* prior to dispensing Opsumit.

I agree that this pharmacy may be audited by the FDA, Actelion, or a designated third-party.

Note: If your inpatient pharmacy needs Opsumit and is not enrolled in the Opsumit REMS Program, contact *Actelion Pathways* at 1-866-228-3546 for assistance in obtaining a 15-day supply of Opsumit for a specific inpatient while initiating enrollment.

Signature | Date

Please visit www.OpsumitREMS.com or call 1-866-ACTELION (1-866-228-3546) for more information about the Opsumit REMS Program.